COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 16/03/2004
C(2004) 906

NOT FOR PUBLICATION

COMMISSION DECISION

of 16/03/2004

amending the marketing authorisation for "PegIntron - Peginterferon alfa-2b", a medicinal product for human use, granted by Decision C(2000)1407

(Text with EEA relevance)

ONLY THE FRENCH AND THE DUTCH TEXTS ARE AUTHENTIC

COMMISSION DECISION

of 16/03/2004

amending the marketing authorisation for "PegIntron - Peginterferon alfa-2b", a medicinal product for human use, granted by Decision C(2000)1407

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1],

Having regard to Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation falling within the scope of Council Regulation (EEC) No 2309/93[2], in particular the third subparagraph of Article 4(5), the first subparagraph of Article 5(7) and the first subparagraph of Article 6(10) thereof,

Having regard to the application submitted by Schering Plough Europe on 21 November 2003 under Article 6(1) of Regulation (EC) No 1085/2003,

Having regard to the opinion of the European Agency for the Evaluation of Medicinal Products, formulated by the Committee for Proprietary Medicinal Products on 21 January 2004,

Whereas:

(1) An examination of the major variation type II to the terms of the marketing authorisation for the medicinal product "PegIntron - Peginterferon alfa-2b", entered in the Community register of medicinal products under Nos EU/1/00/131/031-050 and authorised by Commission Decision C(2000)1407 of 25 May 2000, has shown that the product still complies with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6

[1] OJ L 214, 24.8.1993, p. 1. Regulation as amended by Commission Regulation (EC) No 649/98 (OJ L 88, 24.3.1998, p. 7).
[2] OJ L 159, 27.6.2003, p. 24.

November 2001 on the Community code relating to medicinal products for human use[3].

(2) The application under Article 6(1) of Regulation (EC) No 1085/2003 to modify the marketing authorisation and to amend Decision C(2000)1407 accordingly should therefore be accepted.

(3) In addition, Schering Plough Europe has submitted between 6 October 2003 and 21 January 2004, under Article 4(1) and Article 5(1) of Regulation (EC) No 1085/2003, notifications for minor variations type IA and type IB, respectively, for the medicinal product "PegIntron - Peginterferon alfa-2b".

(4) The European Agency for the Evaluation of Medicinal Products has acknowledged the validity of the type IA notifications and accepted the type IB variations submitted between 6 October 2003 and 21 January 2004, informing the marketing authorisation holder accordingly, and has prepared a list of these notifications. Pursuant to Articles 4(5) and 5(7) of Regulation (EC) No 1085/2003 each of the mentioned variations takes effect from the date of the notification of the acknowledgement of validity or acceptance by the European Agency for the Evaluation of Medicinal Products.

(5) The marketing authorisation should be updated, and Decision C(2000)1407 amended accordingly.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2000)1407 is amended as follows:

1. The list of notifications for minor variations submitted between 6 October 2003 and 21 January 2004 is added to the updated marketing authorisation.

Application number	Scope (Presentations affected)
EMEA/H/C/280/IB/39	42.a.1 (IB) (EU/1/00/131/001-050)

2.Annex I is replaced by the text set out in the Annex to this Decision.

[3] OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2003/63/EC (OJ L 159, 27.6.2003, p. 46).

Article 2

This Decision is addressed to Schering Plough Europe, Rue de Stalle, 73, 1180 Bruxelles, Belgique – Stallestraat, 73 – 1180 Brussel, België.

Done at Brussels, 16/03/2004

For the Commission
Erkki LIIKANEN
Member of the Commission